

REMARKS/DISCUSSION OF ISSUES

By this Amendment, Applicants cancel claim 6 without disclaimer of the underlying subject matter or prejudice against subsequent prosecution. Accordingly, claims 15-33 are pending in the application.

REQUEST FOR NEW NON-FINAL OFFICE ACTION

M.P.E.P. § 706.07(a) provides that:

*"Under present practice, second or any subsequent actions on the merits shall be final, **except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims, nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).**"*

(emphasis added).

The "Final" Office Action of 24 February 2010 provisionally rejects claims 15-33 for the first time over pending U.S. patent application 11/719,310. The Examiner concedes that the reason that this rejection was not presented in the previous Office Action was not due to any amendment by Applicants, but instead due to a typographical error by the Examiner whereby the Examiner previously provisionally rejected claims 9 and 15-16 over U.S. patent application 11/917,310, and not over U.S. patent application 11/719,310.

Therefore, Applicant respectfully submits that the "Final" Office Action of 24 February 2010 introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims, nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).

Accordingly, Applicants respectfully submit that the finality of the Office Action dated 24 February 2010 is improper, and in the event that the present amendment

and arguments do not place the application in condition for allowance, Applicants respectfully request a new Office Action.

DOUBLE PATENTING

The Office Action provisionally rejects pending claims 15-33 as supposedly being obvious over the claims of co-pending U.S. Patent Application No. 11/719,310.

Applicants respectfully traverse these rejections for at least the following reasons.

M.P.E.P. § 804(II)(B)(1) provides that:

"The analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination. . . . Since the analysis employed in an obviousness-type double patenting determination parallels the guidelines for a 35 U.S.C. 103(a) rejection, the factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are employed when making an obvious-type double patenting analysis. These factual inquiries are summarized as follows: (A) Determine the scope and content of a patent claim relative to a claim in the application at issue; (B) Determine the differences between the scope and content of the patent claim as determined in (A) and the claim in the application at issue; (C) Determine the level of ordinary skill in the pertinent art; and (D) Evaluate any objective indicia of nonobviousness. The conclusion of obviousness-type double patenting is made in light of these factual determinations. Any obviousness-type double patenting rejection should make clear: (A) The differences between the inventions defined by the conflicting claims — a claim in the patent compared to a claim in the application; and (B) the reasons why a person of ordinary skill in the art would conclude that the

invention defined in the claim at issue would have been an obvious variation of the invention defined in a claim in the patent."

Applicants respectfully submit that the Office Action does not perform the Graham analysis, does not compare each rejected claim to at least one claim of U.S. Patent Application No. 11/719,310, and does not provide any reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim at issue would have been an obvious variation of the invention defined in a claim in U.S. Patent Application No. 11/719,310.

Therefore, Applicants respectfully submit that the Office Action fails to make a prima facie case that any of the claims of the present application would have been obvious to one of ordinary skill in the art at the time of the invention over the claims of U.S. Patent Application No. 11/719,310.

Accordingly, for at least these reasons, Applicants respectfully request that the Examiner withdraw the provisional obviousness-type double-patenting rejections of claims 15-33 over co-pending U.S. Patent Application No. 11/719,310.

35 U.S.C. §§ 102 and 103

By this Amendment, Applicants cancel claim 6. Accordingly, the rejections of claim 6 under 35 U.S.C. § 102 are deemed to be moot.

The Office Action rejects claims 15-29, 32 and 33 under 35 U.S.C. § 103 over Hainfeld U.S. Patent 6,818,199 ("Hainfeld I") in view of West U.S. Patent Application Publication 2002/0103517 ("West"); claims 15-23, 25-29 and 32-33 under 35 U.S.C. § 103 over Bekeredjian; claims 15-33 under 35 U.S.C. § 103 over Hainfeld I in view of West and further in view of Hainfeld U.S. patent Application Publication 2005/0020869 ("Hainfeld II").

Applicants respectfully traverse those rejections for at least the following reasons.

"Hainfeld I & West"

Claim 15

Among other things, the method of claim 15 includes receiving ultrasound sound wave reflections produced by an ultrasonic wave in an animal or human subject, including ultrasound sound wave reflections from solid metal nano-particles having an acoustic impedance above $35.10^5 \text{ g/cm}^2\text{s}$.

Applicants respectfully submit that no combination of the teachings of Hainfeld I and West would produce a method including this combination of features.

The Office Action does not cite anything in Hainfeld I or West that teaches such a combination of features, and specifically the reception of such ultrasound wave reflections from such nano-particles.

The Office Action states that it would have been "inherent" in "Hainfeld and/or West."

Applicants respectfully disagree.

M.P.E.P. § 2112(IV) provides that:

*"The fact that a certain result or characteristic **may occur or be present** in the prior art **is not sufficient** to establish the inherency of that result or characteristic. In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); In re Oelrich, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence '**must make clear that the missing descriptive matter is necessarily present** in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing **may result** from a given set of circumstances **is not sufficient**.'" In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir.*

1999) (citations omitted)."

(emphasis added)

The cited text at col. 19, lines 10-15 of Hainfeld I explicitly discusses **forms of electromagnetic radiation**. In fact, Hainfeld I uses the term electromagnetic radiation twice in the cited sentence, at the beginning and again at the end. This makes sense as Hainfeld I's disclosure is totally focused on the electromagnetic properties of its nanoparticles for X-ray imaging. One can only conclude that by the plain language of col. 19, lines 10-15, Hainfeld I is referring to low frequency electromagnetic waves.

Furthermore, there is no disclosure or suggestion in Hainfeld I of the acoustic properties of the discussed nano-particles, or using any such acoustic properties in imaging. Other than the cited sentence from column 19, the meaning of which is in dispute, nothing else in Hainfeld I even remotely suggests that Hainfeld I's nano-particles are suitable for, or could be detected with, acoustic imaging techniques. So it is not reasonable to interpret the cited language as pertaining to sound waves, and Hainfeld I certainly does not "inherently" teach receiving ultrasound sound wave reflections from the disclosed metal nano-particles (see M.P.E.P. § 2112(IV) cited above).

Furthermore, the cited reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient (see, e.g., M.P.E.P. § 2121.01).

Here, Hainfeld I does not enable receiving ultrasound sound wave reflections produced by an ultrasonic wave in an animal or human subject, including ultrasound sound wave reflections from solid metal nano-particles having an acoustic impedance above $35 \cdot 10^5 \text{ g/cm}^2\text{s}$, as Hainfeld I makes no mention of any acoustic properties of its nanoparticles, and does not describe or give any example of an equipment for receiving ultrasound sound wave reflections from his nano-particles.

Meanwhile, West is directed to methods of localized heating of nanoshells and imaging based on such heated nanoshells (e.g., near-IR imaging – see, e.g.,

paragraph [0062]). Toward this end, West employs a number of radiation sources, including ultrasound, to heat his nanoshells, and this heat is then detected with near-IR imaging. So, West discloses, for example in claims 12, 15, 33 and 34, that the radiation source for heating the nanoshells may include ultrasound, but West does not disclose that the imaging is performed from ultrasound reflections from the nanoshells (as opposed to infrared reflections from the nanoshells which West discloses and claims).

So Applicants respectfully submit that receiving ultrasound sound wave reflections produced by an ultrasonic wave in an animal or human subject, including ultrasound sound wave reflections from solid metal nano-particles having an acoustic impedance above $35.10^5 \text{ g/cm}^2\text{s}$, is not "*inherent*" in "*Hainfeld and/or West*."

Therefore, for at least these reasons, Applicants respectfully submit that no combination of Hainfeld I and West could produce the method of claim 15.

Applicants also traverse the proposed combination of Hainfeld I and West. The Office Action states that both Hainfeld I and West are directed to ultrasound. However, as explained above, Applicants respectfully submit that neither Hainfeld I nor West pertains to ultrasound imaging, and there would have been no reason to apply West's teachings about *in vivo* use of his nanoshells with Hainfeld I's metal nano-particles.

Therefore, for at least these reasons, Applicants respectfully submit that claim 15 is patentable over Hainfeld I and West. Accordingly, Applicants respectfully request that the rejection of claim 15 over Hainfeld I and West be withdrawn

Claim 16

Among other things, the method of claim 16 includes receiving ultrasound sound wave reflections produced by an ultrasonic wave in a sample or organ, including ultrasound sound wave reflections from solid metal nano-particles having an acoustic impedance above $35.10^5 \text{ g/cm}^2\text{s}$.

For similar reasons to those set forth above with respect to claim 15, Applicants respectfully submit that no combination of the teachings of Hainfeld I and West would produce a method including this combination of features.

Therefore, for at least these reasons, Applicants respectfully submit that claim 16 is patentable over Hainfeld I and West. Accordingly, Applicants respectfully request that the rejection of claim 16 over Hainfeld I and West be withdrawn.

Claims 17-29, 32 and 33

Claims 17-29, 32 and 33 depend variously from claims 15 and 16 and are deemed patentable over Hainfeld I and West for at least the reasons set forth above with respect to claims 15 and 16.

"Bekeredjian"

Claim 15

Among other things, the method of claim 15 includes administering a contrast agent comprising solid metal nano-particles having an acoustic impedance above $35.10^5 \text{ g/cm}^2\text{s}$ to an animal or human subject.

Applicants respectfully submit that Bekeredjian does not disclose or suggest administering **solid metal nano-particles having an acoustic impedance above $35.10^5 \text{ g/cm}^2\text{s}$** . Instead, Bekeredjian discloses attaching gold colloids to the walls of microtubules, and administering the colloidal gold-bound microtubules as the contrast agent.

Applicants respectfully submit that administering colloidal gold-bound microtubules is not administering solid metal nano-particles having an acoustic impedance above $35.10^5 \text{ g/cm}^2\text{s}$.

Nothing in Bekeredjian suggests the administration of solid metal nano-particles having an acoustic impedance above $35.10^5 \text{ g/cm}^2\text{s}$ as a contrast agent.

Therefore, for at least these reasons, Applicants respectfully submit that claim 15 is patentable over Bekeredjian. Accordingly, Applicants respectfully request that the rejection of claim 15 over Bekeredjian be withdrawn

Claim 16

Among other things, the method of claim 16 includes receiving ultrasound sound wave reflections produced by an ultrasonic wave in a sample or organ, including ultrasound sound wave reflections from solid metal nano-particles having an acoustic impedance above $35.10^5 \text{ g/cm}^2\text{s}$.

For similar reasons to those set forth above with respect to claim 15, Applicants respectfully submit that claim 16 is patentable over Bekeredjian. Accordingly, Applicants respectfully request that the rejection of claim 16 over Bekeredjian be withdrawn.

Claims 17-23, 25-18, 32 and 33

Claims 17-23, 25-28, 32 and 33 depend variously from claims 15 and 16 and are deemed patentable over Bekeredjian for at least the reasons set forth above with respect to claims 15 and 16.

"Hainfeld I, West & Hainfeld II"

Claim 15

Among other things, the method of claim 15 includes receiving ultrasound sound wave reflections produced by an ultrasonic wave in an animal or human subject, including ultrasound sound wave reflections from solid metal nano-particles having an acoustic impedance above 35.10^5 g/cm²s.

Applicants respectfully submit that no combination of the teachings of Hainfeld I, West and Hainfeld II would produce a method including this combination of features.

The Office Action does not cite anything in Hainfeld I or West or Hainfeld II that teaches such a combination of features, and specifically the reception of such ultrasound wave reflections from such nano-particles.

The discussion in the Office Action of the rejection of claim 15 over Hainfeld I, West and Hainfeld II focuses on "rhenium" which is a feature of claims 30 and 31, but not claim 15. The Office Action does not explain how the rejection of claim 15 based on Hainfeld I, West and Hainfeld II is supposedly any different between the previous rejection of claim 15 over Hainfeld I and West. Lacking any specific information from the Office Action on the supposed applicability of Hainfeld II to claim 15, and given the statement that "*the rejection over Hainfeld '199 in view of West is applied as above*," Applicants therefore respectfully traverse the rejection of claim 15 over Hainfeld I, West and Hainfeld II for the same reasons as set forth above with respect to the rejection of claim 15 over Hainfeld I and West.

Therefore, for at least these reasons, Applicants respectfully submit that claim 15 is patentable over Hainfeld I, West and Hainfeld II. Accordingly, Applicants respectfully request that the rejection of claim 15 over Hainfeld I, West and Hainfeld II be withdrawn

Claim 16

Among other things, the method of claim 16 includes receiving ultrasound sound wave reflections produced by an ultrasonic wave in a sample or organ, including ultrasound sound wave reflections from solid metal nano-particles having an acoustic impedance above $35.10^5 \text{ g/cm}^2\text{s}$.

For similar reasons to those set forth above with respect to claim 15, Applicants respectfully submit that no combination of the teachings of Hainfeld I, West and Hainfeld II would produce a method including this combination of features.

Therefore, for at least these reasons, Applicants respectfully submit that claim 16 is patentable over Hainfeld I, West and Hainfeld II. Accordingly, Applicants respectfully request that the rejection of claim 16 over Hainfeld I, West and Hainfeld II be withdrawn.

Claims 17-33

Claims 17- 33 depend variously from claims 15 and 16 and are deemed patentable over Hainfeld I, West and Hainfeld II for at least the reasons set forth above with respect to claims 15 and 16, and for the following additional reasons.

Claims 30 and 31

Among other things, the methods of claims 30 and 31 include receiving ultrasound sound wave reflections produced by an ultrasonic wave in an animal or human subject, including ultrasound sound wave reflections from solid rhenium nano-particles having an acoustic impedance above $35.10^5 \text{ g/cm}^2\text{s}$.

Applicant respectfully submits that Hainfeld I, West and Hainfeld II, taken alone or collectively, do not teach any method including such a combination of features.

It appears to be admitted that Hainfeld I, West do not teach the use of such rhenium particles in ultrasonic imaging.

It appears that Hainfeld II is applied to supply this missing teaching.

Applicants respectfully submit that Hainfeld II does not teach or suggest the use of solid rhenium nanoparticles in ultrasonic imaging. Instead, Hainfeld II only teaches the use of nanoparticles made from rhenium in a therapeutic application to enhance energy delivery to target tissue, for example via Compton scattering, the photoelectric effect, and pair production. Hainfeld II does not disclose or suggest the use of rhenium as an imaging contrast agent, and particularly does not disclose or suggest their use or suitability as an imaging contrast agent for acoustic imaging (e.g., ultrasonic sound waves).

Therefore, Applicants respectfully traverse the proposed combination of Hainfeld I, West and Hainfeld II and respectfully submit that any proper combination of Hainfeld I, West and Hainfeld II would not produce the methods of claims 30 & 31.

CONCLUSION

In view of the foregoing explanations, Applicants respectfully request that the Examiner reconsider and reexamine the present application, allow claims 15-33 and pass the application to issue. In the event that there are any outstanding matters remaining in the present application, the Examiner is invited to contact Kenneth D. Springer (Reg. No. 39,843) at (571) 283.0720 to discuss these matters.

Respectfully submitted,

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